UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/046,727	01/17/2002	Graham D. Cook	1142.0125-00	2584

22852 7590 12/20/2005

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER	
KIM, JENNIFER M	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 12/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/046,727	COOK ET AL.	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 6-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,6-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 23, 2005 has been entered.

Action Summary

The rejection of claims 2 and 6 under 35 U.S.C. 102(b) as being anticipated by White (U.S.Patent No. 5,431,916) is hereby expressly withdrawn in view of Applicant's persuasive argument.

The rejection of claims 2 and 6-13 under 35 U.S.C. 103(a) as being unpatentable over Sunshine et al. (U.S.Patent No. 4,522,826) of record in view of White (U.S.Patent No. 5,431,916) is being maintained for the reasons stated in the previous Office Action.

The rejection of claims 1, 2 and 7-13 under 35 U.S.C. 103(a) as being unpatentable over Sunshine et al. (U.S.Patent No. 4,522,826) of record in view of Weng et al. (U.S.Patent No. 5,512,300) and further in view of Ouali et al. (U.S.Patent No. 6287600) is being maintained for the reasons stated in the previous Office Action.

Response to Arguments

Applicants' arguments filed September 23, 2005 have been fully considered but they are not persuasive. With regard to arguments regarding claims 2 and 6-13 unpatentable over Sunshine in view of White, Applicants argue there is no teaching or suggestion in any of the cited references to modify their teachings to arrive at the claimed invention because Sunshine fails to specifically disclose the claimed composition including polyethylene glycol in combination with ibuprofen and diphenhydramine and it is improper for the Office to pick and choose polyethylene glycol from the list of binders in hindsight, as a mere list of compounds in Sunshine does not direct one of ordinary skill in the art to use polyethylene glycol. This is not persuasive because it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In this case, Sunshine teaches polyethylene glycol is a suitable binder to be employed in the composition comprising ibuprofen and diphenhydramine and additionally White also teaches that polyethylene glycol is suitable in the composition comprising ibuprofen and diphenhydramine because polyethylene glycol facilitates the solubility of actives. (column 7, lines 20-30). White further teaches the process of making the encapsulated pharmaceutical composition comprising diphenhydramine and ibuprofen by adding polyethylene glycol. (column 14, claim 15). Therefore one of ordinary skill in the art would have been motivated to

employ well-known suitable binder, polyethylene glycol, well-kwon to be employed in the composition comprising ibuprofen and diphenhydramine by Sunshine and White and suitable for employing for the process of making such composition taught by White to facilitate the solubility of the actives and to successfully formulate a soft gelatin capsules combining the two actives. With regard to arguments regarding claims 1,2 and 7-13 unpatentable over Sunshine in view of Weng and further in view of Quali, Applicants argue that there is no motivation to separate ibuprofen and diphenhydramine in two different layers of Sunshine composition because in Sunshine discusses that composition containing both ibuprofen and diphenhydramine has synergistic properties. This is not persuasive because in deed, Sunshine teaches the combination containing ibuprofen and diphenhydramine results in synergistic combination but it does not mean that a single bilayer tablet comprising ibuprofen and diphenhydramine, each in separate layers is excluded in this synergistic effect. Other words, Sunshine does not suggest that separating ibuprofen and diphenhydramine in different layers within the single bilayer tablet does not result in synergistic effect. It is the Examiner's position that while the combination comprising ibuprofen and diphenhydramine in a bilayer tablet is well known by Sunshine having synergistic effect if well known, it is also known that there is stability problem when ibuprofen and diphenhydramine are physically mixed together in a single layer as taught by Weng et al. Weng et al. clearly report that there is a stability problem in a mixture of diphenhydramine hydrochloride and ibuprofen resulting eutectic mixture. Therefore One would have been motivated to separate bilayer tablet taught by Sunshine containing ibuprofen and diphenhydramine mixed in a single layer to two

different layer in order to avoid the problem of the two active agents forming an eutectic mixture in a single layer within the bilayer tablet. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

In view of the above, the Office Action of 5/23/2005 is deemed proper and asserted with full force and effect herein to obviate applicants' claims. The rejections are restated below for the Applicants' convenience.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2 and 6-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sunshine et al. (U.S.Patent No. 4,522,826) of record in view of White (U.S.Patent No. 5,431,916).

Sunshine et al. teach a pharmaceutical composition comprising 50-400mg ibuprofen and from about 12.5-50mg diphenhydramine elicits an enhanced analgesic and/or anti-inflammatory response. (abstract, column 6, lines 44-45, column 7, lines 1-4, column 14, claim 39). Sunshine et al. also teach that polyethylene glycol is an acceptable carrier to the above composition (column 7, lines 31-35). Sunshine et al. teach the above composition can be formulated in capsules. (column 7, lines 20-23,

claim 41). Sunshine et al. teach that diphenhydramine is commercially available as the hydrochloride salt. (column 1, lines 60-65).

Sunshine et al. do not teach the composition formulated in a **soft gelatin** capsule.

White teaches a composition comprising ibuprofen, diphenhydramine and polyethylene glycol can be formulated in soft gelatin capsule. (column 5, lines 20-65, column 6, lines 65-68, column 7, lines 5-25, Example 11, claims 13 and 15). White discloses that soft gelatin capsules are convenient, portable and easy to swallow and offer a simple means of masking the unpleasant taste and aromas of many pharmaceutically acceptable actives. (column 1, lines 25-31).

It would have been obvious to one of ordinary skill in the art to formulate Sunshine composition into soft gelatin capsules because the composition can be formulated in capsule form in general as taught by Sunshine et al. and it is well-known by White that the composition comprising diphenhydramine and ibuprofen can be formulated in soft gelatin capsules. One would have been motivated to formulate Sunshine composition to soft gelatin capsules in to achieve provide convenient, portable and easy to swallow capsule as taught by White. Further, that soft gelatin capsules are advantageously offer a simple means of masking the unpleasant taste and aromas of many pharmaceutically acceptable actives. One would have been motivated to deliver the composition taught by Sunshine in a soft gelatin capsules that are portable and easy to swallow and to avoid the unpleasant taste of the actives. (ibuprofen and diphenhydramine). Moreover, Applicants' recitation in claim 2 and the intended use of

polyethylene glycol in claim 6 do not represent a patentable limitation in a composition claims since it fails to impart any physical limitation to the composition.

Claims 1, 2 and 7-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sunshine et al. (U.S.Patent No. 4,522,826) of record in view of Weng et al. (U.S.Patent No. 5,512,300) and further in view of Ouali et al. (U.S.Patent No. 6287600).

Sunshine et al. teach a pharmaceutical composition comprising 50-400mg ibuprofen and from about 12.5-50mg diphenhydramine elicits an enhanced analgesic and/or anti-inflammatory response. (abstract, column 6, lines 44-45, column 7, lines 1-4, column 14, claim 39). Sunshine et al. also teach that polyethylene glycol is an acceptable carrier to the above composition (column 7, lines 31-35). Sunshine et al. teach the above composition can be formulated in tablet form or two or more layered tablets. (column 8, lines 4-10). Sunshine et al. teach that diphenhydramine is commercially available as the hydrochloride salt. (column 1, lines 60-65).

Sunshine et al. do not teach the separation of ibuprofen and diphenhydramine in bilayer tablet formulation.

Weng et al. report that it has been recognized that solid dosage forms such as tablets containing ibuprofen and other ingredients tend to exhibit stability problems, including the formulation of low melting point eutectics. (column 1, lines 13-20). Weng et al. report ibuprofen forms low melting point eutectics with diphenhydramine hydrochloride. (column 1, lines 55-57).

Ouali et al. teach that bilayer tablets have advantages in that it is easier and more economical to manufacture than prior compositions that separate a first drug and

a second drug into physically discrete regions of a single dosage form. (column 7, lines 30-41).

It would have been obvious to one of ordinary skill in the art to separate diphenhydramine and ibuprofen of Sunshine composition in a bilayer tablet because diphenhydramine and ibuprofen in a solid dosage forms such as tablets tend to exhibit stability problems including the formation of eutectics as taught by Weng et al. and because bilayer formulation of Sunshine composition has advantage of separate a first drug and a second drug into physically discrete regions of a single dosage form as taught by Ouali et al. One would have been motivated to separate ibuprofen and diphenhydramine bilayer tablet into physically discrete region of a single bilayer tablets in order to avoid the eutectic stability problems of solid dosage form comprising diphenhydramine and ibuprofen reported by Wang et al.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax

phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sreenivasan Padmanabhan
Supervisory Examiner
Art Unit 1617

Jmk
November 30, 2005